REMARKS

Claims 2 and 4-15 are pending in the application. Claims 1, 3, and 16-20 were cancelled in a previous amendment. Support for the amendment to claim 9 appears in the specification at, e.g., page 7, lines 6-8 (disclosing an adeno-associated virus vector) and lines 15-16 (disclosing injection into the ovary). No new subject matter is added. The cancellation of subject matter is not an admission that the subject matter is unpatentable. Applicants reserve the right to pursue the subject matter of all cancelled claims in a continuing application or applications.

Applicants note the Examiner's comment that the oath or declaration is defective because it is unsigned by one of the inventors. Applicants believe this in error, as signed Declarations have been submitted for both of the named inventors. Applicants submit with this response copies of these Declarations.

Rejections under 35 USC 112, first paragraph

Claims 2 and 4-15 are rejected for lack of enablement. The rejection is traversed to the extent it is applied to the claims as amended.

The pending claims are a drawn to a sustained drug delivery device that includes a stably transformed helminth male prepared according to a specified method. The method includes introducing a nucleic acid encoding a bioactive agent, which is provided as part of an adeno-associated virus vector, into an ovary of a female helminth, selecting a helminth that is transformed with the bioactive agent-encoding nucleic acid and adeno-associated virus vector, and crossing the stably transformed female helminth to a non-transformed male helminth. In the final step, a progeny male is isolated that includes the stably transformed bioactive agent-encoding nucleic acid and adeno-associated virus vector.

Types of helminths are described in the specification at, e.g., page 5, lines 5-21, Nucleic acids are well known in the art and are discussed at, e.g., page 7, lines 1-14. Bioactive agents are listed in detail at, e.g., page 8, line 26 to page 9, line 19. The specification additionally discusses methods of introducing the nucleic acids at page 7, lines 15-25, including introduction

into the ovary (page 6, lines 15-16), and of identifying the transformed DNA (page 7, lines 26-29).

Teachings of the prior art supplement these teachings. For example, Miller, WO97/11191 ("Miller"), used by the examiner in the rejections for anticipation (discussed below), describes generally transformation of helminth species.

Applicants submit that the teachings of the specification, coupled with the teachings of the prior art, allow one of ordinary skill in the art to readily practice the full scope of the claimed invention without undue experimentation.

Claims 2 and 4-15 are rejected for lack of written description. The rejection is traversed to the extent it is applied to the claims as amended.

The examiner contends at page 7:

> [O]ne of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by members of the genus of genetically modified helminths. Moreover, the art has recognized that there would be structural variation among the species of helminths.

Applicants respectfully disagree. An objective standard for determining compliance with written description is whether the disclosure of the application relied upon reasonably conveys to persons of ordinary skill in the art that the Applicant had possession of the claimed subject matter as of the date of the invention.[1,2] Applicants submit that the instant specification adequately describes, to one of ordinary skill in the art, the transformed helminth required by the claims.

As is explained above, the specifications provides a detailed disclosure of a stably transformed helminth male prepared according to a specified method helminth made by the steps recited in the claims. The existence of structural variation among species of helminth does not require a conclusion that the claims do not comply with the written description requirement. Moreover, as is detailed above, the disclosure conveys to one of ordinary skill in the art that applicants were in possession of the claimed invention at the time the application was filed.

The present rejection can be compared to the written description issue addressed by the Court in Amgen Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc., 314

[1] *In re Kaslow*, 707 F.2d 1366 (Fed. Cir. 1983)

F.3d 1313, 85 USPQ2d (BNA) 1385 (Fed. Cir. 2003) In this case, the accused infringer argued that the patentee's claims drawn to "vertebrate cells" in U.S. Patent No. 5,756,349 did not meet the written description provision of 35 U.S.C. §112, first paragraph because the patentee failed to sufficiently describe the use of all vertebrate cells but rather only disclosed CHO (hamster) and COS-1 (monkey) cells in the specification.[3] The patentee argued that there are only "minor differences" in applying the method of the disclosed examples to any vertebrate cells, but that those of ordinary skill in the art could "easily" figure out those differences in methodology. Id. The Court reasoned that the word "vertebrate" readily conveyed distinguishing information concerning identity such that one of ordinary skill in the art could "visualize or recognize the identity of the members of the genus. Id. Similarly, Applicants submit that one of ordinary skill in the art would easily recognize Applicants' claimed invention.

Applicants submit that, based on the discussion above and the instant specification, one of ordinary skill in the art would reasonably determine that the Applicant had possession of the claimed subject matter as of the date of the invention. Therefore, Applicants respectfully request withdrawal of the present rejection.

Rejections under 35 USC 102(b)

Claims 2, 5, and 10 are rejected as anticipated by Davis et al., Proc. Nat. Acad. Sci. (USA) 96: 8687-92, 1999) ("Davis"). The rejection is traversed to the extent it is applied to the claims as amended.

Claim 10, from which claims 2 and 5 depend, requires selecting a female helminth stably transformed with a nucleic acid encoding a bioactive agent. Davis does not describe a method that results in stable transformation of a helminth but instead describes transient transformation (see, e.g., the title and page 8692, second full paragraph). Claim 10 as amended is also drawn to a sustained drug delivery device that includes a stably transformed helminth male prepared according to a method that includes introducing a nucleic acid encoding a bioactive agent into an ovary of a female helminth, and in which the nucleic acid is provided as part of an adeno-

[2] *In re Gosteli*, 872 F.2d. 1008 (Fed. Cir. 1989)

according to a method that includes introducing a nucleic acid encoding a bioactive agent into an ovary of a female helminth, and in which the nucleic acid is provided as part of an adeno-associated virus vector. Davis also fails to describe both of these features of the claimed invention. Because Davis fails to describe the invention claimed, Applicants request reconsideration and withdrawal of the rejection for anticipation.

Claims 2 and 4-15 are rejected as anticipated by Miller, WO97/11191 ("Miller"). The rejection is traversed to the extent it is applied to the claims as amended.

Claim 10, from which the remaining claims subject to the rejection depend, has been amended so that it is drawn to a sustained drug delivery device that includes a stably transformed helminth male prepared according to a method that includes introducing a nucleic acid encoding a bioactive agent into an ovary of a female helminth, and in which the nucleic acid is provided as part of an adeno-associated virus vector. Miller does not describe a transformed helminth that is made by introducing into the ovary a nucleic acid that is provided as part of an adeno-virus associated vector. Because Miller fails to describe the invention claimed, Applicants request reconsideration and withdrawal of the rejection for anticipation.

Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 (Reference No. 22493-501).

Respectfully submitted,

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